Section 8
Summary of Safety and Effectiveness

K013024

DEC 0 4 2001

Submitter

NeoMetrics, Inc.
15301 Highway 55 West
Plymouth, MN 55447
Telephone: (763) 559-4440
Fax: (763) 559-7676
Contact Person: Gene Champeau, President
Date: August 31, 2001

Product

Classification Name:	Catheter Guidewire (21 CFR 870.1330)
Common Name:	Guidewire, catheter guidewire, and wire guide
Trade/Proprietary Name:	*Selectiva*™ Guidewire

Substantially Equivalent Product

Lake Region Manufacturing Mandrel Guidewire Assembly (K011084).

Description

The *Selectiva*™ Guidewire is used to facilitate the placement of devices for diagnostic and interventional procedures. The shaft of the device is constructed of PES (polyethersulfone) coated Nitinol or stainless steel with a tapered distal end secured to a platinum or stainless steel helical coil. A selection of distal tapers imparts different tip flexibilities. The guidewire is coated with silicone fluid to improve lubricity.
The *Selectiva*™ Guidewire will be offered in diameters of 0.018" – 0.035" and lengths of 60 cm – 260 cm. It will be supplied sterile, intended for one-time use.

Indications for Use

To facilitate the placement of devices for diagnostic and interventional procedures.
NOTE: These guidewires are not intended for PTCA use.

Physical Characteristics

The *Selectiva*™ Guidewire and the predicate device were compared in all functional and safety tests including dimensional, visual, tip flexibility, tensile strength, torqueability, and coating durability, to demonstrate equivalency in terms of safety and effectiveness. Biocompatibility testing of finished devices has been successfully completed in addition to the independent laboratory testing demonstrating equivalence of materials.

Conclusion

Based on performance data and comparisons of intended use, labeling, and design, the *Selectiva*™ Guidewire is considered substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gene Champeau
President
NeoMetrics, Inc.
15301 Highway 55 West
Plymouth, MN 55447

DEC 0 4 2001

Re: K013024
Seletiva™ Guidewire
Regulation Number: 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: September 6, 2001
Received: September 7, 2001

Dear Mr. Champeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3
Indications for Use

K013024

The NeoMetrics *Selectiva*™ Guidewire is intended to facilitate the placement of devices for diagnostic and interventional procedures.
NOTE: These guidewires are not intended for PTCA use.

Division of Cardiovascular & Respiratory Devices
510(k) Number K013024

Prescription Use ✓
(Per 21 CFR 801.109)